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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,849	03/17/2000	SHIGEKAZU NAGATA	1110-266PCT	5291

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/508,849	NAGATA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 November 2003.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 2-5 and 8-12 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 4,5 and 9 is/are allowed.

6) Claim(s) 2,3, 8 and 10-12 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

1. The Examiner has reconsidered the finality of the rejection of the last Office action and has withdrawn the finality of that action mailed August 26, 2003 as Paper number 17.
  
2. Claims 2-6 and 8-12 are pending.  
Claim 6 has been cancelled.  
Claim 4 has been amended.  
Claims 2-5 and 8-12 are examined on the merits.

### ***Withdrawn Rejections***

#### ***Claim Rejections - 35 USC § 102***

3. The rejection of claim 6 under 35 U.S.C. 102(b) as being anticipated by Takahashi et al. (International Immunology 6(10): 1567-1574, 1994) is withdrawn in light of the cancellation of the claim.
  
4. The rejection of claim 6 under 35 U.S.C. 102(b) as being anticipated by Mita et al. (Biochemical and Biophysical Research Communications 204(2): 468-474, October 28, 1994) is withdrawn in light of the cancellation of the claim.

***New Grounds of Objection***

***Claim Objections***

5. Claim 12 is objected to because of the following informality: the claim contains a period in line 6. It is not clear what text may be missing from the claim if any. Correction is required.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 2, 3, 5, 8 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gray et al. (Nature 312(20/27): 721-724, 1984). Gray discloses isolated polypeptides of claims 2, 3 and 10-12 having an amino acid sequence of natural human Fas ligand (SEQ ID NO: 17) wherein,

(a) all of the 8<sup>th</sup> amino acid to 69<sup>th</sup> amino acids residues as measured from N terminal end are deleted;

(b) at least four amino acid residues, including 128<sup>th</sup> and 131<sup>st</sup> amino acid residues are continuously deleted from the 111<sup>th</sup> amino acid to the 133<sup>rd</sup> amino acid residues as measured from N terminal end;

(b) the 129<sup>th</sup> amino acid and 130<sup>th</sup> amino acid residues as measured from N terminal end are both deleted, and

(c) at least one amino acid residue from 111<sup>th</sup> amino acid to 128<sup>th</sup> amino acid residues or

(d) at least one amino acid residue from 131<sup>st</sup> to 133<sup>rd</sup> amino acid residues as measured from N terminal end is deleted, see attached database sheet. These disclosed polypeptides, which are the same as that claimed have membrane binding activity and induce Fas-mediated apoptotic activity. The isolated DNA coding for the disclosed polypeptides is disclosed on page 722, Figure 1.

8. Claims 2, 3, 5, 8 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Su et al. (Gene 107: 319-321, 1991). Su discloses isolated polypeptides of claims 2, 3 and 10-12 having an amino acid sequence of natural human Fas ligand (SEQ ID NO: 17) wherein,

(a) all of the 8<sup>th</sup> amino acid to 69<sup>th</sup> amino acids residues as measured from N terminal end are deleted;

(b) at least four amino acid residues, including 128<sup>th</sup> and 131<sup>st</sup> amino acid residues are continuously deleted from the 111<sup>th</sup> amino acid to the 133<sup>rd</sup> amino acid residues as measured from N terminal end;

(b) the 129<sup>th</sup> amino acid and 130<sup>th</sup> amino acid residues as measured from N terminal end are both deleted, and

(c) at least one amino acid residue from 111<sup>th</sup> amino acid to 128<sup>th</sup> amino acid residues or

(d) at least one amino acid residue from 131<sup>st</sup> to 133<sup>rd</sup> amino acid residues as measured from N terminal end is deleted, see Result 8 of attached database sheet. These disclosed polypeptides, which are the same as that claimed have membrane binding activity and induce Fas-mediated apoptotic activity. The isolated DNA coding for the disclosed polypeptides is disclosed on page 320, Figure 2.

9. Claims 2, 3, 5, 8 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gardner et al. (The Journal of Immunology 139(2): 476-483, 1987). Gardner discloses isolated polypeptides of claims 2, 3 and 10-12 having an amino acid sequence of natural human Fas ligand (SEQ ID NO: 17) wherein,

(a) all of the 8<sup>th</sup> amino acid to 69<sup>th</sup> amino acids residues as measured from N terminal end are deleted;

(b) at least four amino acid residues, including 128<sup>th</sup> and 131<sup>st</sup> amino acid residues are continuously deleted from the 111<sup>th</sup> amino acid to the 133<sup>rd</sup> amino acid residues as measured from N terminal end;

(b) the 129<sup>th</sup> amino acid and 130<sup>th</sup> amino acid residues as measured from N terminal end are both deleted, and

(c) at least one amino acid residue from 111<sup>th</sup> amino acid to 128<sup>th</sup> amino acid residues or

(d) at least one amino acid residue from 131<sup>st</sup> to 133<sup>rd</sup> amino acid residues as measured from N terminal end is deleted, see attached database sheet. These disclosed polypeptides, which are the same as that claimed have membrane binding activity and induce Fas-mediated apoptotic activity. The isolated DNA coding for the disclosed polypeptides is disclosed on page 480, Figure 3.

10. Claims 2, 3, 5, 8 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Weil and Dautry (Oncogene Research 3: 409-414, 1988). Weil and Dautry disclose isolated polypeptides of claims 2, 3 and 10-12 having an amino acid sequence of natural human Fas ligand (SEQ ID NO: 17) wherein,

- (a) all of the 8<sup>th</sup> amino acid to 69<sup>th</sup> amino acids residues as measured from N terminal end are deleted;
- (b) at least four amino acid residues, including 128<sup>th</sup> and 131<sup>st</sup> amino acid residues are continuously deleted from the 111<sup>th</sup> amino acid to the 133<sup>rd</sup> amino acid residues as measured from N terminal end;
- (b) the 129<sup>th</sup> amino acid and 130<sup>th</sup> amino acid residues as measured from N terminal end are both deleted, and
- (c) at least one amino acid residue from 111<sup>th</sup> amino acid to 128<sup>th</sup> amino acid residues or
- (d) at least one amino acid residue from 131<sup>st</sup> to 133<sup>rd</sup> amino acid residues as measured from N terminal end is deleted, see attached database sheet. These disclosed polypeptides, which are the same as that claimed have membrane binding

activity and induce Fas-mediated apoptotic activity. The isolated DNA coding for the disclosed polypeptides is disclosed on page 411, Figure 1.

11. Claim 4 is rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent Application publication number US 2002/0064869 A1 (May 30, 2002/ filed March 26, 1996). In view of the open language, "...isolated polypeptide *including* the amino acid sequence in SEQ ID NO: 1 or 2" the prior art presented in the instant rejection reads on the claims. This patent application publication discloses sequence 6, an isolated polypeptide that includes the amino acid sequence described in SEQ ID NO: 1 and 2, see attached database sheet and pages 37 and 38 of publication.

12. Claim 4 is rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent Application publication number US 2002/0081647 A1 (June 27, 2002/ filed October 31, 1996). In view of the open language, "...isolated polypeptide *including* the amino acid sequence in SEQ ID NO: 1 or 2" the prior art presented in the instant rejection reads on the claims. This patent application publication discloses sequence 6, an isolated polypeptide that includes the amino acid sequence described in SEQ ID NO: 1 and 2, see attached database sheet and page 55 of publication.

***Allowable Subject Matter***

13. Claim 9 is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, however she can generally be reached between the hours of 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne "Bonnie" Eyler, Ph.D. can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**

  
Alana M. Harris, Ph.D.  
30 March 2004